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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,045	02/25/2004	John Hatlestad	279.B27US1	4409

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EXAMINER	
RANGREJ, SHEETAL	
ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
12/11/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/787,045	HATLESTAD ET AL.	
	Examiner	Art Unit	
	SHEETAL R. RANGREJ	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,14 and 16-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 13-14, 16-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Prosecution History Summary

- Claims 12 and 15 are cancelled.
- Claims 1-11, 13-14, and 16-28 are pending.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim1-6, 8-9, and 11-20 are rejected under 35 U.S.C. 102(e) as being anticipated by LaPorte et al. (U.S. Publication No. 2005/0182389).

1. As per claim LaPorte teaches a medication storage, therapy, and consumption management system, comprising:

-an external, non-ambulatory containment unit configured to accessibly house diuretic medication **(LaPorte: para. 37)**;

-a health management host system coupled to the containment unit in a manner that allows data transmission **(LaPorte: para. 38)**;

-said containment unit including communications and control system that records and transmits data relating to a medication event, said containment unit control system further providing for transmitting and receiving medication therapy data **(LaPorte: para. 44-47)**;

-said health management host system configured to receive data related to the medication event, receive physiologic data, analyze the patient physiologic data and the medication event data, and generate a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data **(LaPorte: para. 44-50)**.

2. As per claim 2, the system of claim 1 is as described. LaPorte further teaches wherein the patient physiological data comprises weight, fluid retention data, data monitored by an implantable device and neuro-hormonal data **(LaPorte: para. 55)**.

3. As per claim 3, the system of claim 1 is as described. LaPorte further teaches wherein the containment unit is further configured to communicate wirelessly with said health management host system **(LaPorte: para. 45; 53)**.

4. As per claim 4, the system of claim 1 is as described. LaPorte further teaches wherein the containment unit is configured with a display device to illustrate a medication therapy strategy **(LaPorte: para. 44-47)**.

5. As per claim 5, the system of claim 4 is as described. LaPorte further teaches wherein the containment unit is configured to receive data from an external source and further configured to transmit such data to the health management host system **(LaPorte: para. 44-47)**.

6. As per claim 6, the system of claim 1 is as described. LaPorte further teaches wherein the containment unit is further configured to notify the patient when it is time to take the medication housed therein **(LaPorte: para. 44-47)**.

7. As per claim 8, the system of claim 1 is as described. LaPorte further teaches wherein said health management host system processes said data related to the medication event data and

said patient physiological data, and in response thereto provides for the generation of an updated medication therapy regimen **(LaPorte: para. 44-50)**.

8. As per claim 9, LaPorte teaches an electronic patient health management system, comprising:

-an implantable medical measurement device for implantably electrically measuring data related to at least one patient physiological health factor including fluid retention data **(LaPorte: para. 41-43)**;

-an external, non-ambulatory a medication therapy management device, configured to house diuretic medication and store data related to patient consumption of medication **(LaPorte: para. 38)**, the medication therapy management device further configured for interrogating the medical measurement device and processing the data retrieved from the medical measurement[[s]] device and the data related to patient consumption of medication **(LaPorte: para. 41-43)**; and

-a patient wellness host system, communicatively coupled to the medication therapy management diagnostic device, configured to receive the processed data and use the processed data to generate a diuretic medication therapy regimen **(LaPorte: para. 48-50)**.

9. As per claim 11, the system of claim 9 is as described. LaPorte further teaches comprising an external medical measurement device for measuring data related to at least one patient physiological health factor **(LaPorte: para. 70)**.

10. As per claim 13, the system of claim 9 is as described. LaPorte further teaches wherein the medical measurement electronic diagnostic device is communicatively coupled to the patient wellness host system via an Internet connection **(LaPorte: para. 48)**.

11. As per claim 14, the system of claim 9 is as described. LaPorte further teaches wherein the medical measurement electronic diagnostic device is communicatively coupled to the patient wellness host system via a wireless communication link **(LaPorte: para. 48)**.

12. As per claim 16, the system of claim 9 is as described. LaPorte further teaches wherein data related to the at least one patient physiological health factor comprises data monitored by an implantable device **(LaPorte: para. 41)**.

13. As per claim 17, the system of claim 9 is as described. LaPorte further teaches wherein data related to the at least one patient physiological health factor comprises weight data **(LaPorte: para. 41)**.

14. As per claim 18, the system of claim 9 is as described. LaPorte further teaches wherein data related to the at least one patient physiological health factor comprises neuro-hormonal data **(LaPorte: para. 41)**.

15. As per claim 19, the system of claim 9 is as described. LaPorte further teaches wherein data related to the at least one patient physiological health factor comprises renal function data **(LaPorte: para. 41)**.

16. As per claim 20, the system of claim 9 is as described. LaPorte further teaches further configured to process said data received in order to develop a therapeutic response **(LaPorte: para. 44-50)**.

17. As per claim 21, the system of claim 20 is as described. LaPorte further teaches wherein the developed therapeutic response comprises revising medication regime, maintaining current medication regime, and recommending a diet plan **(LaPorte: claim 20)**.

18. As per claim 22, the system of claim 9 is as described. LaPorte further teaches wherein the patient wellness host system is a computer, which comprises with a memory, a processor and a user interface **(LaPorte: para. 44-50)**.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 7, 10, and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaPorte et al. (U.S. Publication No. 2005/0182389) in view of Mann et al. (U.S. Publication No. 2004/0147969).

21. As per claim 7, the system of claim 1 is as described. LaPorte does not explicitly teach wherein the containment unit is further configured to communicate a request for a medication re-fill with a pharmacy system when the quantity of the medication is below a pre-determined level.

Mann, however, further teaches wherein the containment unit is further configured to communicate a request for a medication re-fill with a pharmacy system when the quantity of the medication is below a pre-determined level **(Mann: para. 373)**.

One of ordinary skill in the art would have recognized that applying the known technique of Mann would have yielded predictable results and resulted in an improved system. It would have been recognized that applying the technique of LaPorte to the teachings of Mann would have yielded predictable results because the level of ordinary skill in the art demonstrated by the

references applied shows the ability to incorporate such data processing features into similar systems.

22. As per claim 10, the system of claim 9 is as described. LaPorte does not explicitly teach wherein the medication therapy management diagnostic device is further configured to provide a reminder to a patient when it is time to take the medication.

Mann teaches wherein the medication therapy management diagnostic device is further configured to provide a reminder to a patient when it is time to take the medication **(Mann: figure 4)**.

The motivation to combine the teachings is the same as claim 7.

23. As per claim 23, the system of claim 9 is as described. LaPorte does not explicitly teach wherein the medication diagnostic device communicates with the patient wellness host system to alert the wellness manager that the medication level is below a pre-determined level.

Mann, however, teaches wherein the medication diagnostic device communicates with the patient wellness host system to alert the wellness manager that the medication level is below a pre-determined level **(Mann: para. 349)**.

The motivation to combine the teachings is the same as claim 7.

24. As per claim 24, Yarin teaches a method for remote management of medication therapy using an external, non-ambulatory medication containment unit, the method comprising:

-sensing when the an external, non-ambulatory medication containment unit is engaged and recording the same as a medication event **(LaPorte: para. 41-50)**;

-receiving patient physiological data **(LaPorte: para. 41)**;

-processing said patient physiological data and said medication event data **(LaPorte: para. 44-**

50); and

-generating a second therapeutic plan in response to said processing of said patient physiological data and said medication event data **(LaPorte: para. 44-50)**

-implantably electrically sensing fluid retention data; and receiving patient physiological data including the implantably-sensed fluid retention data **(LaPorte: para. 41-50)**.

LaPorte does not explicitly teach a method for remote management of medication therapy using an external, non-ambulatory medication containment unit, the method comprising:

-alerting a patient when it is time to carry out diuretic medication step of a first therapeutic plan.

Mann, however, teaches a method for remote management of medication therapy using an external, non-ambulatory medication containment unit, the method comprising:

-alerting a patient when it is time to carry out diuretic medication step of a first therapeutic plan **(Mann: figure 4)**.

The motivation to combine the teachings is the same as claim 7.

25. As per claim 25, the method of claim 24 is as described. LaPorte does not explicitly teach wherein the alerting step comprises notifying the patient to consume at least one of medication.

Mann, however, teaches wherein the alerting step comprises notifying the patient to consume at least one of medication **(Mann: figure 4)**.

The motivation to combine the teachings is the same as claim 7.

26. As per claim 26, the method of claim 24 is as described. LaPorte further teaches wherein the alerting step comprises causing the an external, non-ambulatory medication containment unit to generate one of the following, an audible sound, to vibrate and to

communicate with a second external device which responsively prompts the patient to act **(LaPorte: para. 130)**.

27. As per claim 27, the method of claim 24 is as described. LaPorte further teaches wherein the receiving step is initiated by an external device transmitting patient physiological data to the external, non-ambulatory containment unit **(LaPorte: para. 41-50)**.

28. As per claim 28, the method of claim 24 is as described. LaPorte teaches wherein the receiving step is initiated when the external, non-ambulatory containment unit interrogates an external device **(LaPorte: para. 41-50)**.

Response to Arguments

29. Applicant's arguments with respect to claims 1-11, 13-14, and 16-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEETAL R. RANGREJ whose telephone number is (571) 270-1368. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/S. R. R./
Examiner, Art Unit 3686
December 7, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686